

ENTERED

December 03, 2021

Nathan Ochsner, Clerk

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION**

MARIA ROBINSON,

Plaintiff,

v.

ETHICON, INC., et al.,

Defendants.§
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CIVIL ACTION H-20-3760

MEMORANDUM OPINION AND ORDER

Pending before the court is a motion to exclude expert testimony of Dr. Niall Galloway filed by defendants Ethicon, Inc., Johnson & Johnson, and Ethicon, LLC (collectively “Ethicon”).¹ Dkt. 130. Upon consideration of the motion, response, reply, status report (Dkt. 169), and the applicable law, the court is of the opinion that the motion should be GRANTED IN PART AND DENIED IN PART.

I. BACKGROUND

Plaintiff Maria Robinson alleges that Ethicon’s TVT-Obturator (“TVT-O”) sling that was implanted to treat her stress urinary incontinence (“SUI”) caused her injury. Dkts. 1, 130. Robinson had surgery to implant the TVT-O in October 2011, and she began complaining of persistent pain within a month of the placement procedure; she was examined by multiple physicians over the next six months.² Dkt. 130, Ex. B; Dkt. 139. Between December 2012 and September 2017, Robinson underwent multiple procedures to remove the mesh comprising the

¹ Ethicon, LLC, was a party at the time the instant motion was filed, but the parties have since filed a stipulation of dismissal as to Ethicon, LLC, only. Dkt. 153.

² While Ethicon objects to multiple aspects of Galloway’s report, Ethicon has not objected to his discussion of the background facts regarding Robinson’s medical treatment, and the court relies on those facts in this order.

TVT-O sling. Dkt. 130, Ex. B. Her ultimate diagnosis is reported as Chronic Pelvic Pain and Pudendal Neuralgia caused the by the TVT-O sling. *Id.* Robinson sued Ethicon on March 28, 2013, asserting products liability claims, negligence, failure to warn, fraudulent concealment, negligent misrepresentation, breach of warranty, and gross negligence. Dkt. 139.

To support her claims, Robinson has designated multiple witnesses including Dr. Niall Galloway as a case-specific expert. Dkt. 130, Ex. B. Galloway is an Associate Professor of Surgery at Emory University School of Medicine in Atlanta, Georgia, where he serves as Medical Director of the Emory Continence Center. *Id.* The Center assesses and treats pelvic floor dysfunction including the condition for which Robinson was treated using the TVT-O. *Id.* Galloway's report is 24-pages long and comprised of seven sections. *Id.* His report includes a discussion of alleged defects and potential adverse medical risks of Ethicon's trans-vaginally placed mesh device generally as well as specific findings regarding Robinson. *Id.* The discussion of general defects comprises close to 60% of Galloway's report, whereas the specific findings comprise roughly 20%. *See id.* On pages 18 through 23, Galloway discusses Robinson's medical history and his differential diagnosis, and he reviews Ethicon's instructions for use ("IFU") of the TVT-O. *Id.* In his opinion, the IFU was incorrect, lacked sufficient information, and misrepresented certain facts. *Id.* He also states that there were safer alternatives to the TVT-O such as a Burch procedure, paravaginal repair, or an autologous fascial sling. *Id.*

Ethicon moves to exclude Galloway's report. Dkt. 130. Ethicon's motion focuses on the content of Galloway's report, not his qualifications as an expert. *Id.* It argues that Galloway's report primarily discusses general rather than specific causation; his specific causation and alternative treatment opinions are irrelevant; he uses legal terms of art and states legal conclusions; and his report speaks to Ethicon's state of mind. *Id.*

II. LEGAL STANDARD

The U.S. Supreme Court acknowledged in *Daubert v. Merrell Dow Pharmaceuticals* that Federal Rule of Evidence 702 serves as the proper standard for determining the admissibility of expert testimony. 509 U.S. 579, 597-98, 113 S. Ct. 2786 (1993). The party offering expert testimony has the burden to prove by a preponderance of the evidence that the proffered testimony satisfies the admissibility requirements of Federal Rule of Evidence 702. *Mathis v. Exxon Corp.*, 302 F.3d 448, 460 (5th Cir. 2002). Rule 702 provides:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. Under *Daubert*, a trial court acts as a "gatekeeper," making a "preliminary assessment of whether the reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93; *see also Kumho Tire v. Carmichael*, 526 U.S. 137, 147, 119 S. Ct. 1167 (1999); *Pipitone v. Biomatrix, Inc.*, 288 F.3d 239, 243-44 (5th Cir. 2002). *Daubert* and its principles apply to both scientific and non-scientific expert testimony. *Kumho Tire*, 526 U.S. at 147. Experts need not be highly qualified to testify, and differences in expertise go to the weight of the testimony, rather than admissibility. *Huss v. Gayden*, 571 F.3d 442, 452 (5th Cir. 2009). Nonetheless, courts need not admit testimony that is based purely on the *ipse dixit* of the expert. *GE v. Joiner*, 522 U.S. 136, 146, 118 S. Ct. 512 (1997); *Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 276 (5th Cir. 1998).

In addition to being qualified, an expert's methodology for developing the basis of his or her opinion must be reliable. *Daubert*, 509 U.S. at 592-93; *Moore*, 151 F.3d at 276. "The expert's

assurances that he has utilized generally accepted scientific methodology is insufficient." *Moore*, 151 F.3d at 276. Even if the expert is qualified and the basis of her opinion is reliable, the underlying methodology must have also been correctly applied to the case's particular facts for her testimony to be relevant. *Daubert*, 509 U.S. at 593; *Knight v. Kirby Inland Marine Inc.*, 482 F.3d 347, 352 (5th Cir. 2007). The party proffering expert testimony has the burden of establishing by a preponderance of the evidence that the challenged expert testimony is admissible. *See* Fed. R. Evid. 104(a); *Moore*, 151 F.3d at 276. The proponent does not have to demonstrate that the testimony is correct, only that the expert is qualified, and that the testimony is relevant and reliable. *Moore*, 151 F.3d at 276.

III. ANALYSIS

A. Classification as a Case-Specific Expert

Ethicon argues that Galloway's general opinions should be excluded because he was identified as a case-specific expert witness rather than a general causation expert. Dkt. 130. In response, Robinson argues that Galloway's general opinions should not be excluded because those opinions reflect his "knowledge, expertise, and methods, upon which he bases his case-specific opinions." Dkt. 139. Robinson further contends that Galloway's designation as a case-specific rather than general causation expert should not be dispositive to whether his opinions regarding general complications of TVT-O and other mesh devices are excludable because those general opinions are relevant to his case-specific differential diagnosis. *See id.*

The court serves as a gatekeeper, assessing whether the expert's reasoning or methodology can be applied to the facts of the case. *See Daubert*, 509 U.S. at 592–93. Thus, the question is whether Galloway's general opinions are relevant and support his case-specific ones. Addressing similar arguments in another case involving Galloway and Ethicon (*Harter*), the district court for

the Southern District of West Virginia ruled that “[a]t trial, counsel must tailor Dr. Galloway’s expert testimony to only his specific causation opinions applicable to [the plaintiff’s] case.” *In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2327 (*Harter*), No. 2:12-cv-00737, 2016 WL 7242550, at *2 (S.D.W. Va. Dec. 14, 2016). While the Southern District of West Virginia’s opinions are not binding on this court, they are persuasive and speak to questions of relevance. The court agrees that the issues in this case are analogous to *Harter* and that the concerns raised by Ethicon in both cases are substantially similar; like in *Harter*, Galloway’s testimony in this case regarding general causation should be cabined such that it pertains specifically to Robinson’s claims. However, Galloway must be able to discuss general causation to the degree that it supports the reliability, relevance, and credibility of his testimony. *See Daubert*, 509 U.S. at 597. Ethicon’s motion to exclude with respect to Galloway’s testimony based on his witness classification is therefore GRANTED IN PART AND DENIED IN PART; Galloway may offer general causation opinions that are necessary to support his specific causation opinions.

B. Opinions Regarding Specific Causation

Galloway opines that Robinson’s injuries were more likely than not a direct result of various alleged defects inherent in TVT-O. Dkt. 130, Ex. B. Citing *Johnson & Johnson v. Batiste*, Ethicon asserts that Galloway’s specific causation opinions should be excluded because he does not state which of the possible defects he points to caused Robinson’s injury. Dkt. 130; *Johnson & Johnson*, No. 05-14-00864-CV, 2015 WL 6751063, at *11 (Tex. App.—Dallas Nov. 5, 2015, pet. dismissed). Ethicon alleges that Galloway’s opinions merely state that the TVT-O generally can cause injuries but not whether a specific defect in the product led to Robinson’s injuries. Dkt. 130. Robinson responds by stating that Galloway’s opinion includes examples of specific defects, mesh-related complications, and Robinson’s particular injuries. Dkt. 139.

Under *Daubert*, Galloway’s opinion must be relevant and reliable. *See Daubert*, 509 U.S. at 592-93; *Moore*, 151 F.3d at 276. That does not mean Galloway’s opinions must be dispositive or conclusive, but simply that his statements “make a fact more or less probable.” *See Fed. R. Evid.* 401(a). The depth of his analysis and whether he has sufficiently demonstrated a connection between specific defects in the TVT-O to Robinson’s injuries speaks to the weight of his testimony, not its admissibility. Therefore, such questions should be reserved for the trier of fact. Ethicon’s motion to exclude with respect to Galloway’s specific causation opinions is DENIED.

C. Opinions Regarding Safer Alternatives

In his report, Galloway proposed that a Burch procedure, paravaginal repair, or autologous fascial sling were all potential alternatives to the TVT-O. Dkt. 130, Ex. B. Ethicon asserts that Galloway’s opinions regarding safer alternative designs should be excluded as irrelevant, unreliable, and speculative. Dkt. 130. Specifically, Ethicon contends that Galloway’s proposed options are not alternative designs but entirely different procedures or products. *Id.* After the instant motion and response were filed, the court granted, in part, Ethicon’s motion for summary judgment, and it dismissed Robinson’s design defect claims. Dkt. 159. Ethicon asserts now that all of Galloway’s opinions about alternative designs should be stricken for the additional reason that they are irrelevant to the remaining claims. Dkt. 169. Robinson argues that evidence of safer alternative procedures is still relevant to the failure to warn and gross negligence claims because it shows Ethicon’s knowledge of the TVT-O’s risks relative to other procedures used to treat SUI, which should have informed Ethicon’s adequate disclosure. *Id.*

The court agrees with Robinson that showing Ethicon knew of safer alternative designs could be probative as to Ethicon’s knowledge of the risks of its design and it could inform the jury regarding the intensity of the warning Ethicon should have provided—if indeed the jury finds a

warning was needed. *Cf. Gerber v. Hoffman-La Roche, Inc.*, 392 F. Supp. 2d 907, 918 (S.D. Tex. 2005) (Atlas, J.) (noting that a warning must disclose the existence and extent of risk as well as “be of an intensity justified by the magnitude of the risk.” (quoting *Pavlides v. Galveston Yacht Basin, Inc.*, 727 F.2d 330, 338 (5th Cir. 1984))). Accordingly, the motion to strike Galloway’s opinions about alternative designs is DENIED; however, Robinson should ensure that his testimony is narrowly tailored to the remaining issues.

D. Opinions That Reference Legal Terms of Art

Ethicon contends that Galloway’s report includes allegedly impermissible legal conclusions and terms of art such as “violated . . . ‘Do No Harm’”; “public health crisis”; “IFU misrepresents”; “unreasonably dangerous”; and “Ethicon did not warn.” Dkt. 130. Ethicon argues that Galloway should be prohibited from offering such opinions. *Id.* To buttress its argument, Ethicon cites related cases where similar portions of Galloway’s opinion were excluded. *See In re: Ethicon, Inc.*, No. 2:12-MD-02327, 2016 WL 4536885, at *4 (S.D.W. Va. Aug. 30, 2016); *Burris v. Ethicon, Inc.*, No. 3:20 CV 1450, 2021 WL 3190747, at *11 (N.D. Ohio July 28, 2021). Robinson responds that Ethicon has misconstrued otherwise admissible expert testimony. Dkt. 139. Robinson cites multiple related cases permitting Galloway to offer similar opinions about whether a transvaginal mesh product had adequate warnings. *Trevino v. Bos. Sci. Corp.*, No. 2:13-CV-01617, 2016 WL 2939521, at *6 (S.D.W. Va. May 19, 2016); *Carlson v. Bos. Sci. Corp.*, No. 2:13-CV-05475, 2015 WL 1931311, at *11 (S.D.W. Va. Apr. 28, 2015).

An opinion is not objectionable simply because it speaks to the ultimate issue. Fed. R. Evid. 704(a). However, Rule 704 is not intended to permit a witness to state legal conclusions. *Owen v. Kerr-McGee Corp.*, 698 F.2d 236, 240 (5th Cir. 1983). Galloway cannot offer testimony such that his statement supplies “the jury with no information other than the expert’s view of how

its verdict should read.” *Id.* The phrases “violated . . . Do No Harm” and “public health crisis” are not legal terms of art or legal conclusions, and thus should not be excluded on that basis. However, Galloway’s opinions that the “IFU misrepresents” information is inadmissible to the extent that he asserts that such misrepresentations were negligent, fraudulent, or otherwise a breach of Ethicon’s duties. Any statements alleging misrepresentation are also inadmissible because they speak to Ethicon’s state of mind. *See* Section III.E *infra*. Similarly, Galloway’s opinions that Ethicon “did not warn” and that its products were “unreasonably dangerous” are not admissible because both state legal conclusions. However, Galloway may discuss Ethicon’s statements or the content of the IFU to illustrate whether they did or did not address certain risks or provide necessary and relevant information. In other words, Robinson’s counsel must tailor Galloway’s testimony to focus on factual issues rather than legal conclusions. Ethicon’s motion to exclude Galloway’s opinions that include legal conclusions and terms of art is GRANTED IN PART AND DENIED IN PART.

E. Opinions Regarding Defendants’ State of Mind

Ethicon asserts that Galloway’s opinions that speak to Ethicon’s state of mind should be excluded. Dkt. 130. Such statements include that Ethicon misrepresented information and had knowledge of “misleading or untrue” statements in the IFU regarding the TVT-O’s safety and performance. *Id.* Ethicon notes that courts have excluded similar testimony in other cases related to its products. *See In re Ethicon, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-CV-4301, 2014 WL 186872, at *6 (S.D.W. Va. Jan. 15, 2014) (“Ethicon’s knowledge, state of mind, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury.”); *Huskey v. Ethicon, Inc.*, 29 F. Supp.

3d 691, 703 (S.D.W. Va. 2014). Robinson contends that Ethicon fails to discuss any specific instances where Galloway speaks to Ethicon's state of mind. Dkt. 139.

The Fifth Circuit has held that state-of-mind testimony should be excluded as impermissible when it does not "assist the trier of fact to understand the evidence or to determine a fact in issue." *See* Fed. R. Evid. 702; *Marlin v. Moody Nat'l Bank, N.A.*, 248 F. App'x 534, 541 (5th Cir. 2007) ("[A]n expert's conclusory assertions regarding a defendant's state of mind are not helpful or admissible."); *Salas v. Carpenter*, 980 F.2d 299, 305 (5th Cir. 1992) (holding that an expert witness's testimony regarding whether defendant's lack of concern constituted deliberate indifference or conscious disregard were inadmissible and did not aid the jury). The expert's role is to explain evidence to the jury and to act as the source of evidence for the jury, not provide legal conclusions. *See Salas*, 980 F.2d at 305.

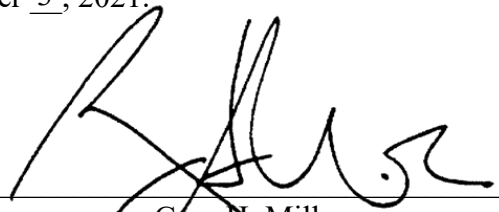
Robinson's contention that Ethicon does not cite any specific instance where Galloway's opinion speaks to Ethicon's state of mind is simply not true. *See* Dkt. 130, 139. For example, Galloway states that the "IFU misrepresents" multiple facts. Dkt. 130, Ex. B. Misrepresentation is "[t]he act or an instance of making a false or misleading assertion about something, usually with the intent to deceive." *Misrepresentation*, Black's Law Dictionary (11th ed. 2019). While misrepresentation does not strictly require scienter, the term is often associated with negligence and fraud, both of which speak to the defendant's knowledge and state of mind. *See id.*; *Scienter*, Black's Law Dictionary (11th ed. 2019). Thus, any of Galloway's statements asserting that Ethicon "misrepresented" information must be excluded. However, Galloway is permitted to testify that the IFU is factually incorrect, does not address the likelihood of adverse events, or does not provide sufficient information regarding potential medical issues such as "frequency, severity, lack of responsiveness to treatment, and permanence of complications associated with the

product.” *See* Dkt. 130, Ex. B. Therefore, Galloway’s opinion is excluded to the degree it specifically speaks to the Ethicon’s state of mind rather than facts regarding the content of Ethicon’s IFU or other related statements Ethicon made regarding the TVT-O. Ethicon’s motion to exclude with respect to Galloway’s opinions regarding its state of mind is GRANTED.

IV. CONCLUSION

Ethicon’s motion to exclude Galloway’s expert testimony (Dkt. 130) is GRANTED IN PART AND DENIED IN PART. Its motion to exclude is GRANTED regarding Galloway’s statements that speak to Ethicon’s state of mind; GRANTED IN PART AND DENIED IN PART regarding Ethicon’s request to exclude Galloway’s testimony based on his witness classification and to exclude his opinions that include legal conclusions and terms of art; and DENIED regarding Galloway’s specific causation opinions and safer alternative design opinions. Robinson is cautioned to tailor Galloway’s testimony to the remaining issues.

Signed at Houston, Texas on December 3, 2021.



Gray H. Miller
Senior United States District Judge